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| 09/938,454 | 08/24/2001 | Carol J. Collins | NEU-40 | 2232 |
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| PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | SHEIKH, HUMERA N | |
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| DATE MAILED: 12/03/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/938,454

Applicant(s)

COLLINS ET AL.

Examiner

Humera N. Sheikh

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 CFR §1.114, the Amendment, Applicant's Arguments/Remarks and request for extension of time (1 month-granted), all filed 07/26/04 is acknowledged. Examiner also acknowledges receipt of the second Supplemental Information Disclosure Statement (IDS), filed on 02/27/03.

Claims 1-24 are pending. No amendments to the claims have been made. Claims 1-24 are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunkel *et al.* (US Pat. No. 6,524,598 B2).

Sunkel *et al.* teach cosmetic compositions comprising organopolysiloxane elastomers and silicone oils wherein the composition may be in the form of a foundation, *mascara*, eye shadows, powders, blushers, lip color and the like (see reference column 2, lines 35-55); Examples, particularly Example II and claims 1, 13 and 20.

Silicone oils include *cyclomethicone* (see Examples). Film-forming agents taught include *polyurethanes* (col. 12, lines 8-11). Pigments, such as *mica* are listed at column 16, line 65 – col. 17, line 35. Solidifying agents (*i.e.*, waxes) are present at a concentration of from about 0 to about 90% (col. 14, lines 55-65). Exemplary organopolysiloxanes are taught at column 3, line 66 – col. 4, line 13.

Example II at column 23 demonstrates a mascara composition comprising elastomer gels, silicone oils, pigments and the like. The mascara composition is applied to the lashes and/or eyebrows to provide softening, moisturization and conditioning.

The prior art explicitly teaches the use of organopolysiloxane elastomers, silicone oils and gels in mascara formulations. The Applicant's have not demonstrated any criticality based on the claimed limitation of less than about 1%, by weight, of wax. Sunkel *et al.* at column 14, lines 55-65, teach that solidifying agents (*i.e.*, waxes) are present at a concentration of from about 0 to about 90%. The formulations of Sunkel *et al.* are not limited to the Examples recited in the '598 patent, which include the use of wax, since generally, the solidifying agents (*i.e.*, waxes) can be contained at a concentration of from 0-90%, as taught by Sunkel *et al.* Therefore,

based on the delineated teachings, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shukuzaki *et al.* (US Pat. No. 5, 266,321) in view of Sunkel *et al.* (US Pat. No. 6,524,598 B2).

Shukuzaki *et al.* teach an oily make-up cosmetic comprising a silicone gel composition, which comprises a partially crosslinked organopolysiloxane polymeric compound and a low viscosity silicone oil (see reference column 2); (col.7); (col.8, lines 47-56); and examples. Specific examples of the low viscosity oils are: dimethylpolysiloxane, methylphenylpolysiloxane, octamethylcyclotetrasiloxane, decamethylcyclopentasiloxane and the like (col. 7, lines 3-16). Various cosmetic powders, such as mica can be included in the composition (col. 7, lines 32-45). The make-up cosmetic can be applied to a foundation, eye shadow, face powder, lip stick and the like and can take various forms including a solid, stick and the like (col. 8, lines 53-56).

Shukuzaki is deficient only in the sense that he does not explicitly teach the make-up cosmetic in the form of mascara.

Sunkel et al. teach cosmetic compositions comprising organopolysiloxane elastomers and silicone oils wherein the composition may be in the form of a foundation, *mascara*, eye shadows, powders, blushers, lip color and the like (see reference column 2, lines 35-55); Examples, particularly Example II and claims 1, 13 and 20.

It would have been obvious to one of ordinary skill in the pharmaceutical art at the time the invention was made to use the teachings of Sunkel *et al.* within the teachings of Shukuzaki *et al.* because Sunkel *et al.* explicitly teach cosmetic compositions comprising organopolysiloxane elastomers and silicone oils wherein the cosmetic composition may be in various forms, such as foundation, *mascara*, eye shadows, powders, lip color, blushers and the like and similarly, Shukuzaki *et al.* teach polyorganosiloxane elastomers and silicone oils formulated in a make-up cosmetic wherein the composition can be applied to foundations, eye shadows, face powder, lip stick and the like and can take various forms including a solid, stick. The expected result would be an improved, cosmetic composition, such as in the form of mascara, that provides softening, moisturizing and conditioning properties.

Prior Art made of record and deemed relevant by the Examiner:

US Pat. No. 5, 412,004 Tachibana *et al.* 02/1994

Response to Arguments

Applicant's arguments filed 07/26/04 have been fully considered but they are not persuasive.

Firstly, Applicant argued, "No support is provided for the Examiner's contention that 'the incorporation of polysiloxane elastomers in various forms of cosmetics are deemed to be functionally equivalent'. Applicant also argues that they 'do not agree that cosmetics always use the same ingredients.'

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These arguments have been thoroughly considered, but were not found persuasive. Shukuzaki *et al.* teach the use of organopolysiloxane elastomers in various cosmetic forms, such as foundations, eye shadow, face powder, lipstick and the like. Shukuzaki *et al.* do not teach a mascara composition. Sunkel *et al.* are relied upon to remedy this only deficiency of Shukuzaki *et al.* by explicitly teaching organopolysiloxane elastomers in combination with silicone oils, contained in an array of cosmetic forms, which include, mascara, among others, such as foundations, eye shadow, face powder, lipstick and the like. The secondary reference of Sunkel demonstrates that the organopolysiloxane elastomers are suitable and effective in solid and semi-solid formulations and teaches similar forms as those taught by the primary reference of Shukuzaki *et al.* Therefore ample motivation is provided by the teachings of the prior art. Moreover, regarding functional equivalence, the Examiner notes that the selection of a known material based on its suitability for its intended purpose is obvious and supports a *prima facie* obviousness determination, absent a clear showing of unexpected results attributable to the Applicant's specific selection. Since both references teach the use of the same ingredient, polyorganosiloxane elastomers, used in a similar field of endeavor (*i.e.*, cosmetics), the properties imparted by that ingredient would also be the same or similar. Additionally, the discovery of a new property for a well-known ingredient does not impart patentability to the product itself, absent a clear showing of unexpected results.

Secondly, Applicant argued, "Sunkel *et al.* comprises 11.25% of wax. Sunkel does not teach mascara that comprises less than about 1%, by weight, of wax. Rather, Sunkel discloses a mascara that comprises about 10 times more wax."

These arguments were not found persuasive. Although Sunkel demonstrates a mascara formulation comprising greater than 1% wax or specifically, 11.25% wax as stated by Applicant, it is the Examiner's position that the Examples are not limiting to the formulations of Sunkel since Sunkel *et al.* teach at column 14, lines 55-65, that solidifying agents, such as waxes, for example, are present at a concentration of from about 0 to about 90%. The teaching of "about 0%" of solidifying agents, of which wax is included, would clearly read on the 'less than about 1%, by weight, of wax' as instantly claimed. Additionally, Applicants have not demonstrated any criticality with regards to the instant limitation of 'less than about 1%, by weight, of wax'. The mascara of Sunkel *et al.* provides softening, moisturization and conditioning benefits and thus, the waxes contained therein, would not be deemed detrimental to the formulation itself.

Thirdly, Applicant argued regarding the PCT Appln. No. WO 00/74519 (assigned to Revlon Consumer Products), stating, "Waxes provide certain undesirable properties...waxes cause mascaras to increase in viscosity during storage. Thus, the reduction of the amount of wax is important."

This argument has been considered, but was not found persuasive. Shukuzaki *et al.* recognize the significance of obtaining viscosity levels that provide for proper gel structures in the cosmetic formulations. For instance, Shukuzaki *et al.* teach, at column 7, lines 24-31, that if the amount of polyorganosiloxane compound is too small, the composition becomes fluid-viscous and does not form a proper gel structure, whereas if the amount of polyorganosiloxane is too large, a soft gel composition is difficult to produce. The prior art also teaches the use of 'low-viscosity' silicone oils to provide for 'better make-up effects and superior stability'.

Lastly, Applicant argued, "Applicants refer to the '519 Application to support the point that waxes provide certain undesirable properties, and thus the minimization or removal of waxes from the mascara would be desirable and beneficial."

This argument was not found persuasive, since as delineated above, the prior art recognizes using particular amounts of ingredients (*i.e.*, siloxane elastomers, gels, etc.) to obtain formulations that provide for suitable viscosity levels to obtain stable and superior cosmetic effects with aesthetic properties. Additionally, Examiner notes that one of ordinary skill in the cosmetic art would be fully capable of determining suitable amounts of wax through the use of routine or manipulative experimentation to obtain the best possible results, based on the intended purpose, as these are indeed variable parameters.

For the reasons advanced above, the instant invention is rendered *prima facie* obvious over the cited prior art of record.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh *H.N.S.*

Patent Examiner

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December 01, 2004

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